APMP GUIDELINES FOR

ACCEPTING A QUALITY MANAGEMENT SYSTEM

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Contents

1. INTRODUCTION

The CIPM mutual recognition arrangement (MRA) requires National Metrology Institutes (NMIs) and Designated Institutes (DIs) to establish and maintain a Quality Management System (QMS). This shall be used to

- establish mutual confidence in the measurement and calibration certificates issued by the NMI/DI, and
- thereby provide governments and other parties with a secure technical foundation for wider agreements related to international trade, commerce, and regulatory affairs.

The CIPM document *CIPM MRA-G-12* indicates the requirements for a quality management system to be recognised, but it is left to the regional metrology organisations to develop specific guidelines for acceptable quality management systems.

This document gives the APMP guidelines for accepting a quality management system, and the evidence required to demonstrate compliance with those guidelines.

2. REQUIREMENTS

For the APMP to accept the quality management system of an NMI/DI as satisfying the requirements of the CIPM MRA, evidence is required, demonstrating:

i the implementation of a quality management system satisfying *ISO/IEC 17025*

ii (or *ISO 17034* for certified reference material producers), and ii. the technical competencies required to provide calibration and measurement services that can deliver the uncertainties claimed.

2.1. APMP PATHWAYS

Compliance can be demonstrated by following one of the three pathways:

a. Third party accreditation, using approved technical peers, or

b. Certification to *ISO 9001* and attestation by technical peers, or

c. Attestation by a Review Team consisting of QMS experts and technical peers. This may be organised by the NMI/DI or by another recognised body, such as an accreditation body or APAC.

Notes:

- Third party accreditation shall be obtained from an accreditation body that is accredited to *ISO/IEC 17011* and a signatory to the APAC or ILAC MRAs.

- Certification to *ISO 9001* must be obtained from a conformity assessment body that is accredited to *ISO/IEC 17021* by a signatory of the APAC MRA or to be a signatory of International Accreditation Forum Multilateral Recognition Agreements (IAF MLA).
- Selection Criteria for technical peers and QMS experts are given in the appendices of this document.

3. Review Approval and Monitoring

To accept new CMC entries, APMP conducts the review of both technical and quality management system in parallel as detailed in *APMP-G-1*, *APMP-G-3* and *APMP-MRAG-06* (the flow diagram of CMC entry, acceptance and QMS acceptance).

Technical Committee for Quality System (TCQS) working group 2 (WG2) conducts the review of the quality management system for a new CMC entry as follows:

1. The NMI/DI seeking a new CMC submits the required evidence to the TCQS Chair for review.
2. The TCQS Chair appoints a coordinator within WG2.
3. The coordinator appoints two other WG2 members to conduct the review of the documents submitted by the NMI/DI as per the requirements detailed in this chapter.

The two reviewers conduct independent reviews and write their report in the form *APMP-QS-D-03* and provide to the coordinator.

4. The coordinator and the TCQS Chair check the reports and compiles the information into a report in the form *APMP-QS-D-07*. When the quality management system is deemed to be approved, the completed *APMP-QS-D07* form along with the *APMP-QS-D-03* forms as its basis will be sent by the TCQS Chair to the relevant TC Chair and the submitting NMI/DI.
5. The TC Chair will compile the technical review and the QMS review to complete the intra-RMO review.

APMP-MRA-G-06 pictures the entire workflow of the procedures detailed in *APMP-G1*, *APMP-G-3* and this document *APMP-MRA-G-05*.

For the re-approval of existing CMCs, APMP mandates peer reviews every five years. The CMCs and the existence of the quality management system supporting the CMCs including new entries and existing items are reviewed during the peer review and recorded in the report. The peer review/assessment reports (both quality and technical) need to be submitted to the TCQS Chair with the next annual report for the monitoring process. These reports will be made available to TCQS members and be reviewed at the TCQS meeting in conjunction with the annual report review and presentation. TCQS can request and review additional information when some aspect might be missing.

3.1. Review and Approval

Review needs to include the following items specified in *CIPM MRA-G-12* section 3.1

a) a diagram showing the organisational structure of the institute;

b) quality management system mechanisms;

c)detailed table of the contents of the quality management system documentation

(e.g., of the quality manual when available);

d) list of administrative and technical procedures;

e) table of cross references between *ISO/IEC 17025* and/or *ISO 17034* and the quality management system documentation of the institute;

f) list of CMCs covered by the quality management system;

g) customer complaints – process employed and statistics;

h) nonconforming work – process employed and corrective actions;

i) report on internal audits;

j) status of management reviews;

k) outcomes of peer-reviews where these have taken place;

l) plan and implement action to address major identified risks and opportunities.

Furthermore, attach as appendix the following information upon necessity.

m) participation in RMO projects and activities;

n) other available knowledge and experience; updates on facilities, measurement infrastructure and improved metrological capabilities, participation in scientific and training activities, visits and consultation with technical experts from other RMOs.

Note: The above aspects are usually reviewed and reported on by the peer review technical team and accreditation body or QMS experts. NMIs/DIs should make sure that all aspects are covered under these activities.

3.1.1. PATHWAY(A)

NMIs/DIs following pathway (A) must submit the following evidence to APMP[1]:

- Copies of accreditation certificate(s) or equivalent accreditation information
- Scope(s) of accreditation
- Names and affiliations of the technical assessors or technical peers
- Assessment report(s)/technical peer review report(s)

[1] Please see 3.3.1 Reporting Requirements – PATHWAY (A)

- Technical peer approval from related TC or EC

3.1.2. PATHWAY(B)

NMIs/DIs following pathway (B) must submit the following evidence to APMP[2]:

- *ISO 9001* Quality Management System certificate(s), with details of the areas covered by each certificate, or a statement that the certification covers all technical areas of the NMI/DI.
- Report(s) from the technical peer review(s). This must be prepared following the assessment review visits and shall report against the relevant[3] technical requirements of the appropriate standard/guide. The following are minimum reporting requirements[4]:

  o Scope of the review

  o Schedule of the review

  o Names and affiliations of the technical peers

  o Findings of the Review Team (especially the non-conformances)

  o Listing of the NMI/DI's capabilities

  o Any other comments

  o Attestation by the technical peers

  o Signatures and dates
- A final attestation by the technical peers, or at least by the leader of the Review Team, stating that all the non-conformances have been satisfactorily addressed.
- Technical peer approval from related TC or EC

3.1.3. PATHWAY(C)

NMIs/DIs following pathway (C) must submit the following evidence to APMP[5]:

[2] Please see 3.3.2 Reporting Requirements – PATHWAYS (B) and (C)

[3] A requirement would not be considered 'relevant' if the function/activity were not carried out by the NMI/DI, e.g. sampling.

[4] Refer to "RECOMMENDED FORMATS" in the appendices of this document.

[5] Please see 3.3.2 Reporting Requirements – PATHWAYS (B) and (C)

- A report by the Review Team of QMS experts and technical peers. This report must be prepared following the assessment review visits and shall report against the relevant[6] technical requirements of the appropriate standard/guide. The following are minimum reporting requirements[7]:
    - Scope of the review
    - Schedule of the review
    - Names and affiliations of the technical peers
    - Names, affiliations, qualifications, and experience of the QMS experts.
    - Findings of the review (especially the non-conformances)
    - Listing of the NMI/DI's capabilities
    - Any other comments
    - Attestation by the reviewers
    - Signatures and dates
- Final attestation by the reviewers, or at least by the leader of the Review Team, stating that all the non-conformances have been satisfactorily addressed
- Technical peer approval from related TC or EC
- QMS expert approval from TCQS

3.2. MONITORING AND REAPPROVAL

3.2.1. ONGOING MONITORING OF QMS

- To provide evidence that APMP QMS is operating correctly, each institute shall submit an annual report[8] to the TCQS four weeks before the annual TCQS meeting.
- The quality manager, or representative, of the NMI/DI shall also submit the annual report and present the key issues as an abstract of their submitted annual report to the TCQS meeting. The submitted annual report will include a record of any recent assessments or review. Such record include technical peer reviewer's report, accreditation body's assessment/survey report, certification body's assessment/survey report and QMS expert's report, depending on the selected pathway. The NMI/DI should submit the

[6] A requirement would not be considered 'relevant' if the function/activity were not carried out by the NMI/DI, e.g. sampling.

[7] For details, please see 3.3.2 Reporting requirements –PATHWAYS (B) and (C)

[8] For details please see ([APMP-QS-D-02]: QMS Annual report)

records in accordance with the pathway selected for the relevant scope under the reviews conducted during that year. The TCQS must also be informed of any major changes affecting the QMS (including major changes to key staff, facilities, and equipment) that could negatively affect the NMI/DI's ability to provide measurement services covered by their CMCs.

- Reports of peer reviews/accreditation assessments during the year's term also need to be attached to the annual report.

3.2.2. Reapproval of a QMS in an Intra-APMP Review

- An assessment and/or peer review of every technical area (covered by one of the RMO technical committees), and the QMS, must be conducted at least once every five years.

Note, in addition to periodic specialist technical area assessments, institutes that follow pathway (A) are audited frequently by their accreditation body (usually every year). The reports of these surveillance visits provide further evidence for acceptance of an institute's QMS by confirming the satisfactory continuous operation of a QMS across the scope of accreditation.

- To approve the QMS of each NMI/DI, the TCQS requires the NMI/DI to provide evidence that all current CMCs are covered by the QMS and that the requirement for periodic review of technical areas, and the QMS, has been met.

The quality manager, or representative, of the NMI/DI shall present a report8 to the annual TCQS meeting, which also have reports of peer reviews/accreditation assessments attached.

- The following is evidence that TCQS has reapproved the NMI/DI QMS:
  - The NMI/DI annual report provided to the TCQS Chair
  - The peer review reports written by peers who are approved by the relevant TC
  - Annual report presentation to TCQS

3.2.3. APMP Report to JCRB

The APMP representative to the JCRB must report on the QMS status of all APMP members (NMIs and DIs) at the JCRB meeting. It is the responsibility of the TCQS Chair to prepare this report.

3.3. Reporting Requirements for Approval and Reapproval

3.3.1. Reporting Requirements-Pathway(A)

An NMI/DI following pathway (A) shall submit the reports prepared by its accreditation body of technical reviews and surveillance audits. Any format used by the accreditation body is acceptable. If the accreditation body does not report in English, technical peer-review reports in English should be provided as well.

Reports should include the following information:

a) name of the NMI/DI

b) date(s), time, location, scope and program of the on-site visit

c) Names and affiliations of the assessment team

The name(s) and affiliation(s) of the reviewer(s) /assessor(s), with the Review Team leader clearly identified. If different reviewers were responsible for different areas, this should be noted.

d) Scope of the assessment

- what has been assessed (specific technical areas and/or QMS)
- the standard / guide used for the assessment, including the version (e.g. *ISO/IEC 17025:2017*, *ISO 17034:2016*)

e) List of NMI/DI measurement capabilities

The report should list the measurement capabilities approved / recognised by the assessment, with reference to corresponding entries in the accredited scope, and indicating that the reviewers recognise the NMI/DI as having the competence to deliver ordinarily. If a measurement capability is submitted as an attachment of the report, it shall be approved, dated and signed by the reviewers or acknowledged by relevant TC Chair.

f) Review findings

Review findings against all the aspects specified in *CIPM MRA-G-13*. The assessment findings should be given, and the report should refer to the relevant sub-clauses of the standard. The statements also need to include the following as required in the *CIPM MRA-G12*.

a. Comments on the NMI/DI's nonconformities and, where applicable, actions taken to correct nonconformities.

b. The adequacy of the NMI/DI's quality management system and its implementation to demonstrate the conformity with the requirements of the CIPM MRA

c. An explanation of any significant differences of opinion between the reviewer and the NMI/DI

g) Signatures and dates

Note: the TCQS may request additional information, such as details of corrective actions taken to address any non-conformances identified during the assessment.

3.3.2. REPORTING REQUIREMENTS-PATHWAY(B) AND (C)

An NMI/DI following pathway (B) or (C) and that undergoes a peer review process, is required to obtain a report from the Review Team for submission to APMP. The minimum requirements for this report are described below.

The peer-review report may be accompanied by a more detailed report, with additional and perhaps more extensive information. Ideally, this detailed report should be prepared at the same time as the peer-review report.

a) name of the NMI/DI

b) date(s), time, location, scope and program of the on-site visit

c) Identification of technical peers and quality management system experts The names and affiliations of the peer reviewers, with the team leader clearly identified. If different reviewers were responsible for different areas, this should be noted too.

d) Scope of the review

- what was reviewed (specific areas in the laboratory)
- the standard/guide, or parts thereof, used for the review, including the version (e.g. *ISO/IEC 17025:2017*, *ISO 17034:2016*).

e) List of NMI/DI measurement capabilities

The report should list the measurement capabilities approved / recognised by the assessment, with reference to corresponding entries in the accredited scope, and indicating that the reviewers recognise the NMI/DI as having the competence to deliver ordinarily. If a measurement capability is submitted as an attachment of the report, it shall be approved, dated and signed by the reviewers or acknowledged by relevant TC Chair.

f) Review findings against all the aspects specified in *CIPM MRA-G-13*. The assessment findings should be given, and the report should refer to the relevant sub-clauses of the standard. The statements also need to include the following as required in the *CIPM MRA-G12*.

a. Comments on the NMI/DI's nonconformities and, where applicable, actions taken to correct nonconformities.

b. The adequacy of the NMI/DI's quality management system and its implementation to demonstrate the conformity with the requirements of the CIPM MRA

c. An explanation of any significant differences of opinion between the reviewer and the NMI/DI

g) Reviewer attestation

The reviewers must attest to the finding that (subject to satisfactory resolution of any non-conformances raised during the review) the laboratory has demonstrated:

- the implementation of a quality management system that satisfies the standard/guide, and that

- the laboratory has the technical competencies required to provide calibration and measurement services that can deliver the uncertainties claimed.

h) Signatures and dates.

Note 1: The APMP may ask for additional information, such as details of corrective actions taken to address any non-conformances identified during the assessment.

Note 2: If any non-conformances arise during the review, a second attestation must be made by reviewers, or by the team leader of the review, stating that all the nonconformances have been satisfactorily addressed by appropriate corrective actions.

REFERENCES

[APMP-MRA-G-06] Flow diagram of CMC entry, acceptance and QMS acceptance

[APMP-QS-D-01] QMS questionnaire form

[APMP-QS-D-02] QMS annual report form

[APMP-QS-D-03] QMS report by reviewer

[APMP-QS-D-04] Technical peer approval form

[APMP-QS-D-05] QMS expert approval form

[APMP-QS-D-07] QMS report reviewed by TCQS Chair and coordinator

TERMS

- Technical Peers and Assessors

  A technical peer (peer) is an expert who meets the requirements for a peer reviewer given in the appendix to *CIPM MRA-G-12*. Every technical peer must be approved by the appropriate TC Chair, using the TCQS form (*APMP-QS-D04*: Technical peer approval form). In the case where a technical peer or assessor is the TC Chair himself or herself, he/she needs to be approved by the APMP EC.

  A technical assessor (assessor) is an expert appointed by an accreditation body who has not been approved by the appropriate TC Chair and so may not meet the peer-reviewer requirements in CIPM MRA-G-12.

  When an accreditation body appoints a technical expert, who has been approved by the appropriate TC Chair for the assessment or review then the term technical peer applies.

  Only technical peers may recognise peer review and approve CMCs under the CIPM MRA.

- Recognition of a QMS

  In the *CIPM MRA-G-12*, the verb approve is used in association with acceptance of a QMS. However, in this document, the verb recognise is used instead of approve, with an equivalent meaning intended.

- Assessment and Review of an NMI/DI

  An assessment (or reassessment) is carried out when an institute follows pathway (A). In that case, an accreditation body is responsible for the assessment of the QMS and will appoint technical peers, or assessors, to look at calibration and measurement capabilities.

  A review is carried out when an institute follows pathway (B) or (C). In that case, periodic reviews will be organised by the institute to generate evidence in support of their CMC claims.

TECHNICAL PEERS, QMS EXPERTS

- Technical peers and QMS experts must be independent of the institute being assessed or reviewed.

  Technical peers must be acceptable to the relevant technical committee (TC). [9]

[9] The guidelines for 'selecting visiting peer reviewers', given in the appendix to CIPM MRA-G-12, also apply.

Acceptance shall be obtained formally from the TC Chair, before an assessment or review, by providing suitable information about the candidate, using the form (*APMPQS-D-04*: Technical peer approval form). The TC chair's approval shall be recorded on the same form (section C).

Technical peers should:

1) have appropriate technical competence,
2) have had some formal training in laboratory assessments, and
3) have had some laboratory assessment experience.
4) Items 2 and 3 may not be necessary if the technical assessors/technical peers work with, or under the guidance of, a QMS expert during the review.

- Technical peers shall be from an NMI/DI with similar capabilities to, or better than, those of the institute being assessed or reviewed. The published CMCs of the technical peer's institute can be used to make this assessment.

  In exceptional circumstances, technical peers working for organisations outside the NMI/DI community may be used, provided they are jointly approved by the relevant TC and the APMP Executive Committee.

- It is discouraged to approve the same peer reviewer as the last time. TCCs shall monitor the history of approved peer reviewers of each NMI/DI. (RESOLUTION TCC 29-01)

  NOTE: Technical peers for pathway (B) especially needs to demonstrate competence in *ISO/IEC 17025* and also for *ISO 17034* when reference material production is in concern, in order to compensate the gap between *ISO 9001* and *ISO/IEC 17025* and/or *ISO 17034* for certified reference material producers.

A QMS expert shall have substantial experience in quality management system. For NMIs/DIs following pathway (C), the acceptance shall be obtained formally from the **TCQS Chair**, before an assessment or review, by providing suitable information about the candidate, using the form (*APMP-QS-D-05*: QMS expert approval form). The **TCQS Chair**'s approval shall be recorded on the same form (section C). The expert could be someone who normally conducts, or in the past has conducted, assessments on behalf of an accreditation body that is accredited to *ISO/IEC 17011* and is a signatory to the ILAC or APAC MRA. In some cases, the expert could have obtained QMS experience as the Quality Manager of an NMI/DI, or as the Chair of an RMO quality management systems technical committee (e.g. TCQS of APMP, TCQ of EURAMET, etc.), or in some other role with similar responsibilities for quality management system.

RECOMMENDATION FORMATS

- **Format for the Findings of the Review Team**

In column 1 (Clause), the clause number or the clause title in the relevant standard shall be entered.

In column 2 (Code), use **OK** for "Complies with requirement", **NC** for "Nonconformance found" and **NR** for "Not reviewed".

Clause	**Code (OK/NC/NR)**	**Description of a non-conformance or any other comments**
Impartiality		
Equipment		
4.1		
6.4		

- **Listing of NMI/DI's Measurement Capabilities**

Measurand (Quantity)	Instrument/ Artefact	Range	Measurement Conditions/ Independent Variables	Expanded Uncertainty		Comments (if necessary)
				coverage factor (k)	level of confidence	

ABBREVIATIONS USED IN THIS DOCUMENT

CIPM	International Committee for Weights and Measures
APAC	Asia Pacific Accreditation Cooperation
ILAC	International Laboratory Accreditation Cooperation
IAF	International Accreditation Forum
CMC	Calibration and measurement capabilities Details could be found in document CIPM-MRA-G13
TC	APMP Technical Committee
EC	APMP Executive Committee
TCQS	Technical Committee for Quality System (TCQS)

Record of Revisions

No.	Date of Revision	Meeting	Chap/Sec	Description of Revisions
1.0	12/10/2022	APMP GA 2022	All	New document superseding APMPQS2